

INCISION TRAINER FOR OPHTHALMOLOGICAL SURGERY

BACKGROUND

1. Field of the Invention

The present invention relates to systems and methods for simulating certain anatomic features of the human eye to allow trainees to practice invasive procedures upon a realistic anatomic replica. In particular, the present invention provides in one embodiment a simulation of a human cornea to permit incisions to be practiced thereupon.

2. Description of the Related Art

It is well understood in the ophthalmological art that the lens contributes only one third of the total focusing power of the eye, while the remaining two-thirds arises from the convex shape of the anterior corneal surface. It is further understood that very small changes in corneal shape may have a dramatic effect on the precision with which light rays are brought to the focus upon the retina. Incisions made in the cornea or anterior sclera during ophthalmological procedures, therefore, may change the refraction of the eye. It appears that surgically induced change in corneal contour is less significant for more peripheral incisions in the sclera or limbus than for those incisions that involve the cornea. A substantial literature in the ophthalmological art supports the premise that smaller incisions are associated with less surgically induced change in corneal contour, earlier visual recovery after surgery, more stable refraction, and better uncorrected postoperative visual acuity. Furthermore, it has been determined that the placement of sutures to close access incisions may induce astigmatism. Although for larger incisions, suture placement has been necessary to close the path between the interior of the eye and its external surface, placing sutures in the surface of the eye may combined with natural wound healing characteristics to alter the shape of the eye and thereby induce astigmatism. For all these reasons, surgeons have determined that minimizing the size of corneal incisions would be desirable.

Surgical access to the interior portions of the eye has been the subject of intensive research to discover the most effective and least traumatic technique. Scleral tunnel incisions were introduced in the early 1980s in order to provide better wound healing with less surgically induced astigmatism; these incisions permitted wider surgical exposure for cataract extraction and were modified for phacoemulsification. In 1990, the sutureless incision was developed, which utilized a longer scleral tunnel with a grooved floor in the meridian of the incision. This incision could be stretched to admit a folded lens following phacoemulsification, and could remain unsutured thereafter. The corneal entry point of this tunneled incision was shaped as a one-way valve or corneal lip so that the incision would self-seal. The temporal, sutureless, clear corneal incision for cataract surgery was described in 1992. It has now become a favored technique for cataract surgery internationally in conjunction with foldable or small-incision intraocular lenses. The development of sutureless, astigmatically neutral incisions has combined with advances in intraocular lens technology to permit major advances in the surgical treatment of cataracts. Clear corneal incisions have gained ascendancy over recent years for a variety of cataract extraction techniques.

For cataract surgery using small-incision techniques, the incision for which the surgical tools are inserted generally approximates the circumference of the tools that are inserted therethrough. If the incision is too small, corneal tissue

surrounding the incision may be damaged by stretching or by thermal injury. If the incision is too large, leakage from the unsutured passageway may occur after surgery with potentially disastrous consequences. The angle of the incision is also important to allow optimal surgical access while still permitting self-sealing. A number of variations on surgical techniques exists for performing clear corneal incisions. An initial incision method involved making incision in a single plane. Subsequently, a perpendicular groove of 300 to 400 microns in depth was added to the incision to form a superior lip, resulting in less tendency for tearing. Special surgical tools may be used to form these delicate incisions. For example, a diamond knife which is beveled on all edges may be used whose dimensions are specifically constructed so that the tip of the diamond is a preselected distance (e.g., 1.75 mm) from a line joining the shoulders of the blade. Using such a knife, an incision may be constructed by applanation of the wall of the eye, so that the tip is at the anterior edge of the vascular arcade. From that position, the knife may be advanced in the plane of the cornea until a line that joins the shoulders reaches the incision, at which point the tip is tilted down through Descemet's membrane before the initial plane is re-established, at which point the knife is inserted to the hilt. As a result, a rectangular incision 3 mm wide and 2 mm long is formed. It is understood that incisions of less than 3 mm width in the peripheral cornea are astigmatism neutral as long as they are constructed with sufficient accuracy. Other methods for forming clear corneal incisions are familiar to skilled practitioners in the field. Often, anatomic landmarks, such as the angle of the sclera, the angle of the iris or the curvature of the cornea, are used to guide the direction for inserting the ophthalmological scalpel as the incision is formed. For many clear corneal incisions, widths between 2.5 mm and 3 mm are commonplace. These incisions permit subsequent access to the cataract using the variety of techniques well-known in the art. While the incisions described above are generally familiar to ophthalmologic surgeons, innovation in technique and instrumentation is ongoing. New surgical incisions and new surgical tools may be devised to facilitate access to intraocular structures through the clear cornea or through other anatomic areas of the eye.

The size of these incisions, the complexity of their geometry and their location in the optically sensitive corneal region makes it imperative that they be made cleanly and accurately. There is little if any room for error. A poorly made incision may require corrective steps to be taken that eliminate the incision's purported advantages and that introduce other potential complications. Without both training and practice, it is difficult for physicians to form these incisions consistently and precisely. Not only must trainees and less experienced surgeons be able to practice established techniques using commonplace instrumentation, but also must well established surgeons have an opportunity to practice in order to learn a new surgical method or to try out a new surgical tool.

Currently, a surgeon wishing to learn an unfamiliar skill and gain proficiency therein has a limited number of options for learning and practicing. In time-honored manner, the surgeon may practice in vitro using an animal eye or may initially try out an instrument or practice a skill on a patient during actual surgery. There are limitations to both options. The animal eye in a fresh or preserved state may lack of the surgical characteristics of a living human patient's eye. The animal eye may also introduce sanitary and hazardous material issues. Using the patient undergoing eye surgery as a laboratory for learning new skills or experimenting with new instruments is even more undesirable.